to the nature of the preventive control and its role in the facility's food safety system, in a timeframe that exceeds the first 90 calendar days of production of the applicable animal food.

(b) A qualified auditor must conduct an onsite audit (§ 507.135(a)).

(c)(1) To be a preventive controls qualified individual, the individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility; and

(2) To be a qualified auditor, a qualified individual must have technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function.

(d) All applicable training in the development and application of risk-based preventive controls must be documented in records, including the date of the training, the type of training, and the person(s) trained.

§ 507.55 Implementation records required for this subpart.

(a) You must establish and maintain the following records documenting implementation of the food safety plan:

(1) Documentation, as required by § 507.36(b), of the basis for not establishing a preventive control in accordance with § 507.36(a);

(2) Records that document the monitoring of preventive controls;

(3) Records that document corrective actions;

(4) Records that document verification, including, as applicable, those related to:

(i) Validation;

(ii) Verification of monitoring;

(iii) Verification of corrective actions;

(iv) Calibration of process monitoring and verification instruments;

(v) Product testing;

(vi) Environmental monitoring;

(vii) Records review; and

(viii) Reanalysis;

(5) Records that document the supply-chain program; and

(6) Records that document applicable training for the preventive controls qualified individual and the qualified auditor.

(b) The records that you must establish and maintain are subject to the requirements of subpart F of this part.

Subpart D—Withdrawal of a Qualified Facility Exemption

§ 507.60 Circumstances that may lead FDA to withdraw a qualified facility exemption.

(a) FDA may withdraw a qualified facility exemption under § 507.5(d):

(1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or

(2) If FDA determines that it is necessary to protect the public (human or animal) health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at such facility.

(b) Before FDA issues an order to withdraw a qualified facility exemption, FDA:

(1) May consider one or more other actions to protect the public (human or animal) health or mitigate a foodborne illness outbreak, including, a warning letter, recall, administrative detention, suspension of registration, refusal of animal food offered for import, seizure, and injunction;

(2) Must notify the owner, operator, or agent in charge of the facility, in writing of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the facility to respond in writing, within 15 calendar days of the date of receipt of the notification, to FDA's notification; and